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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------|-------------|----------------------|-------------------------|------------------|
| 09/381,055 | 10/30/2000 | Aziz Asghar | 1103326-0590 | 3456 |
| 7590 11/26/2004 | | EXAMINER | | |
| White & Case | | | LUKTON, DAVID | |
| Patent Departme | ent | | | |
| 1155 Avenue of the Americas | | | ART UNIT | PAPER NUMBER |
| New York, NY 10036-2787 | | | 1653 | |
| | | | DATE MAILED: 11/26/2004 | , |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|
| | 09/381,055 | ASGHAR ET AL. |
| Office Action Summary | Examiner | Art Unit |
| | David Lukton | 1653 |
| The MAILING DATE of this communication Period for Reply | n appears on the cover sheet w | ith the correspondence address |
| A SHORTENED STATUTORY PERIOD FOR R THE MAILING DATE OF THIS COMMUNICATION - Extensions of time may be available under the provisions of 37 Claffer SIX (6) MONTHS from the mailing date of this communication - If the period for reply specified above is less than thirty (30) days, - If NO period for reply is specified above, the maximum statutory p - Failure to reply within the set or extended period for reply will, by any reply received by the Office later than three months after the earned patent term adjustment. See 37 CFR 1.704(b). | ON. FR 1.136(a). In no event, however, may a on. a reply within the statutory minimum of thir period will apply and will expire SIX (6) MON statute. Cause the application to become A | reply be timely filed ty (30) days will be considered timely. THS from the mailing date of this communication. |
| Status | | |
| 1) Responsive to communication(s) filed on (| 05 December 2001. | |
| l | This action is non-final. | |
| Since this application is in condition for aller | owance except for formal matt | ers, prosecution as to the merits is |
| closed in accordance with the practice und | der <i>Ex parte Quayle</i> , 1935 C.D |). 11, 453 O.G. 213. |
| Disposition of Claims | | |
| 4) Claim(s) 1-12 is/are pending in the applica | | |
| 4a) Of the above claim(s) is/are with | ndrawn from consideration. | |
| 5) Claim(s) is/are allowed. | | |
| 6) Claim(s) is/are rejected. 7) Claim(s) is/are objected to. | | |
| 7) Claim(s) is/are objected to. 8) Claim(s) <u>1-12</u> are subject to restriction and | t/or election requirement | |
| | aror crossion requirement. | |
| Application Papers | | |
| 9) The specification is objected to by the Exam | | |
| 10) The drawing(s) filed on is/are: a) Applicant may not request that any objection to | accepted or b) objected to t | by the Examiner. |
| Replacement drawing sheet(s) including the co | rrection is required if the drawing | ce. See 37 CFR 1.85(a). |
| 11) The oath or declaration is objected to by the | e Examiner. Note the attached | Office Action or form PTO-152 |
| Priority under 35 U.S.C. § 119 | | |
| 12) Acknowledgment is made of a claim for fore | eign priority under 35 U.S.C. & | 119(a)-(d) or (f) |
| a) ☐ All b) ☐ Some * c) ☐ None of: | o i o o o o o o o o o o o o o o o o o o | (1) |
| Certified copies of the priority docum | nents have been received. | |
| 2. Certified copies of the priority docum | nents have been received in Ap | oplication No, |
| 3. Copies of the certified copies of the p | | received in this National Stage |
| application from the International Bur | | |
| * See the attached detailed Office action for a | list of the certified copies not r | received. |
| Attachment(s) | | |
| 1) Notice of References Cited (PTO-892) | 4) Intender o | Immory (DTO 442) |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s) | ımmary (PTO-413) /Mail Date |
| Information Disclosure Statement(s) (PTO-1449 or PTO/SB/Paper No(s)/Mail Date | /08) 5) \(\bigcap \) Notice of Inf 6) \(\bigcap \) Other: \(\bigcap \) | formal Patent Application (PTO-152) - |

Pursuant to preliminary amendment (filed 10/30/00), claims 1-3, 9-12 have been amended. Claims 1-12 remain pending.

Restriction to one of the following inventions is required under 35 U.S.C. §121:

- I. Claim 9, drawn to a method of treating IBS by administering an NMDA receptor antagonist.
- II. Claims 10-12, drawn to a composition comprising an NMDA receptor antagonist.

Claims 1-8 are not grouped, since they are drawn to a "use". In the event that these claims are amended so as to fall within the bounds of a proper statutory class of invention (in conformance with U.S. practice), these claims will be grouped appropriately.

The claimed inventions are distinct.

Were it the case that claim 9 were drawn to a method of using a composition, or that claim 10 were drawn to a compound *per se*, Groups II and I would be related as product and process of use. In either of these cases, the respective inventions could be shown to be distinct if either or both of the following could be shown: (1)

the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). As it happens, NMDA receptor antagonists have been asserted in the prior art to be useful for treating a variety of diseases in addition to IBS. Nevertheless, in the event that Group II is elected, and claims therein found allowable, claims which are drawn to a method of making and using the (allowed) composition will be rejoined for further examination.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect a disclosed specie for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

A "specie" is a specific compound with a fully defined structure.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are witten in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37

CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103 of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached at 571-272-0925. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

PATENT EXAMERER
GROUP 1800